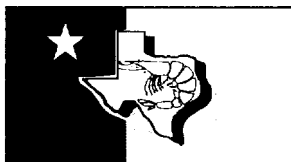


HARLINGEN SHRIMP FARMS, LTD.

PH (956) 233-5723

FAX (956) 233-9779



6506 '99 DEC -2 P1:45

November 23, 1999

Dockets Management Branch
(HFA-305)
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855

RE: Docket No. 99D-2638, Use of Medicated Feeds for Minor Species; Draft CPG

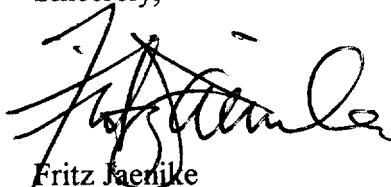
To Whom it May Concern,

Recently I received and reviewed the new Compliance Policy Guide issued by the CVM regarding the extra label use of medicated feeds for minor species. We are shrimp growers in Texas and have been working through an **INAD** for pursuing approval of oxytetracycline for shrimp disease control. We have been collecting data for several years and are hopeful that FDA will approve this drug's use for shrimp in the U.S. soon.

Since the FDA approval process for new drugs in aquaculture is long and detailed, any policy changes which would make the extra label use of drugs for minor use species more flexible should be supported. It should be noted that there is a great diversity of species and disease situations which exist for "minor species" in aquaculture. Making the extra label process more accessible for minor species is a step in the right direction, however not a panacea. The FDA should increase funding and staff working on new drug approvals so that specific feed formulations and dosages can be utilized by more minor species producers. For instance a shrimp farmer cannot utilize a salmon feed which has been extra labeled because the feed formulation and approved dosage of drug will not be effective to prevent mortalities associated with specific shrimp diseases.

Please evaluate what can be done to accomplish a faster turn around time in the FDA new drug approval process. Thank you for the opportunity to comment.

Sincerely,


Fritz Jaenike
99D-2638

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ROUTE 3 BOX 300K CENTERLINE ROAD
LOS FRESNOS, TX 78566

HARLINGEN SHRIMP FARMS, LTD.

Route 3 Box 300K Centerline Road
Los Fresnos, Texas 78566



DOCKET'S MANAGEMENT BRANCH
HF'A-305
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE RM. 1061
ROCKVILLE, MD 20852

20852/0000

